

***Remarks***

Claims 1-15, 19 and 20 have been amended; claims 16-18 have been withdrawn; claim 21 has been added, the specification has been amended and replacement drawings for Figures 1-3 are submitted by way of the present amendment.

In the outstanding Office Action, claims 16-18 were withdrawn from consideration; Figures 1-3 were objected to because they were not clear; the Abstract was objected to because it contains the word “said;” claims 1-15, 19 and 20 were rejected under 35 U.S.C. Section 112, 2<sup>nd</sup> paragraph, as indefinite; claims 1-9, 12-15, 19 and 20 were rejected under 35 U.S.C. Section 102(b) as anticipated by U.S. Patent No. 3,605,123 (Hahn); and claims 10 and 11 were rejected under 35 U.S.C. Section 103(a) as unpatentable over Hahn.

***Specification***

In response to the objection to the Abstract, the Abstract has been amended to clarify the invention. In particular, the word “said” has been removed and the abstract has been edited to further clarify the description of the invention. Applicants respectfully submit that the amendments raise no question of new matter.

***Drawing Objections***

In response to the drawing objections, replacement drawing Figures 1-3 are being submitted as an attachment to the present amendment. The replacement Figures 1-3 provide a clearer indication of the content of the figures than the original photographs. The replacement drawing Figures 1-3 correspond to drawings made from the photographs that made up the original Figures 1-3. Applicants respectfully submit that support for the replacement Figures 1-3 is provided by original Figures 1-3 and the description of these figures contained in the specification. Therefore, Applicants respectfully submit that the replacement drawings raise no question of new matter.

**AMENDMENTS TO THE DRAWINGS**

The attached sheet of Drawings includes changes to Figures 1, 2, and 3. This sheet, which includes Figures 1, 2, and 3, replaces the original sheet of Drawings including Figures 1, 2, and 3.

Attachment: One (1) Sheet of Replacement Drawings showing Figures 1, 2, and 3

### ***112 Claim Rejections***

Claims 1-15, 19 and 20 were rejected under 35 U.S.C. Section 112, 2<sup>nd</sup> paragraph, as indefinite. In response to the rejection of the claims under 35 U.S.C. Section 112, second paragraph, the claims have been amended in accordance with the suggestions indicated in the outstanding Office Action. In addition, claims 1-20 have been amended to clarify the invention and to place the claims in a form more compatible to U.S. patent practice. Support for the amendments is provided by the Figures and throughout the text of the specification. Therefore, applicants respectfully submit that the claims raise no issue of new matter.

### ***102 Claim Rejections***

Claims 1-9, 12-15, 19 and 20 were rejected under 35 U.S.C. Section 102(b) as anticipated by Hahn. Applicants respectfully traverse the rejection.

Hahn discloses a permanent implant for bone tissue which has a dense cast or wrought base portion of high strength metal, and a porous metal layer overlying and bonded to the base portion.<sup>1</sup> In particular, Hahn discloses a prosthesis **10** that includes a pin or shaft **11** and ball **12**.<sup>2</sup> In addition, Hahn discloses the prosthesis **10** may be composed of metals such as titanium.<sup>3</sup>

Further, Hahn discloses the titanium prosthesis **10** is coated, on the pin or shaft **11**, with a *thin* porous layer of titanium **13**.<sup>4</sup> In particular, Hahn discloses that the coating thickness is approximately 0.1 inch and the preferred thickness is from about 0.015 to about 0.030 inches.<sup>5</sup>

Moreover, Hahn discloses a process for providing a high strength bond between the coating **13** and base metal shaft **11** using a plasma flame. In particular, Hahn discloses *no* porosity or practically no porosity exists at the interface between the coating **13** and surface of the base metal shaft **11** and the porosity gradually increasing porosity, along with pore size and pore density, in moving away from the interface between the surface of the base metal and the

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<sup>1</sup> Hahn at Abstract.

<sup>2</sup> *Id.* at column 3, lines 30-33.

<sup>3</sup> *Id.* at column 3, lines 33-35.

<sup>4</sup> *Id.* at column 3, lines 43-45.

<sup>5</sup> *Id.* at column 3, lines 47-54.

coating 13. Furthermore, Hahn discloses renderings of actual photographs of magnified sections of bone 20, 30; pin or shaft 21 and coating 22, 32.<sup>6</sup>

However, Hahn nowhere discloses, as recited in claim 1:

[a] layer (2'''), which can be arranged on an implant (1) for bone or tissue structure (5), that constitutes a boundary or barrier for the purpose of increasing retention and has a substantial thickness (T), said layer (2''') further comprising:

*a channel network (6) that gives the layer a substantial porosity,*

*wherein the channel network (6) is designed with mouths (3, 4) which face towards a surface of the layer and whose respective cross-sectional diameters (D) at the surface (2a') of the layer are substantially less than the respective extents (H) of the channels in and down into the layer as seen from said surface (2a') (emphasis added).*

That is, though Hahn discloses a layer 13 that becomes progressively more porous when moving away from the metal base 11, Hahn nowhere discloses a layer (2''') with “a channel network” that:

- (1) “gives the layer a *substantial* porosity;” and
- (2) “is designed with mouths (3, 4) which face towards a surface of the layer and whose respective cross-sectional diameters (D) at the surface (2a') of the layer are substantially less than the respective extents (H) of the channels,” as recited in claim 1 (emphasis added).<sup>7</sup>

Specifically, Hahn nowhere addresses the dimensions of the channels (i.e., “D” and “H” as recited in claim 1) or any relationship between these dimensions.

Further, Hahn nowhere discloses “the layer has a surface roughness in the range of 0.4 – 5  $\mu\text{m}$ ,” as recited in claim 2; “the layer has high degree of porosity, with a number  $1 \times 10^7 - 1 \times 10^{10}$  pores/ $\text{cm}^3$ ,” as recited in claim 9; and “the layer comprises a titanium oxide layer,” as recited in claim 11.

Furthermore, Hahn nowhere discloses a method using “anodic oxidation,” as recited in claim 16, which electrochemically oxidizes the layer.

<sup>6</sup> *Id.* at FIG. 2, FIG. 3; column 3, lines 55-66; and column 5, lines 25-42.

<sup>7</sup> *Id.* at column 3, lines 55-66.

Further, Hahn nowhere discloses “contiguous channel branches” that “extend through at least a greater part of the layer from said surface to a transition from the layer to the implant,” as recited in claim 2. In addition, independent claims 15 and 16 contain similar wording to that recited in claim 1 and, as noted above, the limitations of this wording are *not* disclosed by Hahn.

Thus, it is respectfully submitted that Hahn does not disclose, anticipate or inherently teach the limitations of at least claims 1, 2, 9, 11, 15 and 16. Therefore, it is respectfully submitted that claims 1, 15, and 16, and claims dependent thereon, patentably distinguish over Hahn.

### ***103 Claim Rejections***

Claims 10-11 were rejected under 35 U.S.C. Section 103(a) as unpatentable over Hahn. Applicants respectfully traverse the rejection.

Claims 10-11 are dependent on claim 1. As discussed above, claim 1 is not disclosed by Hahn. Therefore, at least for the reasons discussed above, claims 10 and 11 are not disclosed by Hahn.

The outstanding Office Action attempts to overcome the deficiencies of Hahn with the suggestion of obviousness.<sup>8</sup> However, obviousness cannot overcome all of the deficiencies of Hahn as discussed below.

Hahn nowhere discloses, as recited in claim 1:

[a] layer (2’”), which can be arranged on an implant (1) for bone or tissue structure (5), that constitutes a boundary or barrier for the purpose of increasing retention and has a substantial thickness (T), said layer (2’”) further comprising:

*a channel network (6) that gives the layer a substantial porosity,*

*wherein the channel network (6) is designed with mouths (3, 4) which face towards a surface of the layer and whose respective cross-sectional diameters (D) at the surface (2a’) of the layer are substantially less than the respective extents (H) of the channels in and down into the layer as seen from said surface (2a’) (emphasis added).*

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<sup>8</sup> Outstanding Office Action at page 9, lines 4-14.

That is, though Hahn discloses a layer 13 that becomes progressively more porous when moving away from the metal base 11, Hahn nowhere discloses layer (2''') with "a channel network" that:

- (1) "gives the layer a substantial porosity;" and
- (2) "is designed with mouths (3, 4) which face towards a surface of the layer and whose respective cross-sectional diameters (D) at the surface (2a') of the layer are substantially less than the respective extents (H) of the channels," as recited in claim 1.<sup>9</sup> Specifically, Hahn nowhere addresses the dimensions of the channels (i.e., "D" and "H" as recited in claim 1) or any relationship between these dimensions.

Thus, it is respectfully submitted that Hahn nowhere discloses, suggests or makes obvious the limitations of claims 1, 10 and 11. Therefore, claims 1, 10 and 11; and claims dependent thereon, patentably distinguish over Hahn.

### **New Claims**

Claim 21 has been added by way of the present amendment. Claim 21 was derived from original claim 7. Thus, Applicants respectfully submit that new claim 21 is supported by original claim 7 and raises no question of new matter. Therefore, at least for the reasons discussed above, Applicants respectfully submit that Claim 21 patentably distinguishes over Hahn.

### ***Conclusion***

In view of the above amendments and remarks, reconsideration and allowance of the pending claims are respectfully requested.

Applicants believe that the present application is in condition for allowance, and an early indication of the same is respectfully requested.

If the Examiner has any questions or requires clarification, the Examiner may contact the undersigned so that this Application may continue to be expeditiously advanced. In the event the

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<sup>9</sup> *Id.* at column 3, lines 55-66.

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Examiner believes an interview might serve to advance the prosecution of this application in any way, the undersigned is available at the telephone number noted below.

The Director is hereby authorized to charge any fees, or credit any overpayment, associated with this communication, including any extension fees, to Deposit Account No. 22-0185.

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Respectfully submitted,

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